

**REMARKS**

Reconsideration and allowance are respectively requested in view of the foregoing amendments and the following remarks.

Claims 1-33 are pending in this application.

Claims 1, 2, 13, 16, and 18 have been amended.

**Regarding the § 103 Rejections**

Claims 1-4, 6, 14-16, 18-22, and 27-32 were rejected under 35 U.S.C. § 103(a) as being rendered obvious by Bonomini (U.S. Patent No. 4,269,708).

Applicant respectfully points out that Bonomini does not teach, allude to or render obvious a continuous renal replacement therapy device “that is adapted to enable a patient to wear the whole device.” Instead, Bonomini teaches and renders obvious a partially wearable dialysis module along with a portable, not wearable, portion having a 20-liter dialysis solution supply tank (Col. 6, lines 10-15) and a replaceable filter cartridge. (Fig. 2) The 20-liter Bonomini dialysis solution tank is too heavy for a patient to wear and is part of the portable portion of the Bonomini device. Thus, Bonomini teaches a two portion device wherein part of the device is wearable and another part is merely portable. When the wearable portion of the Bonomini device is worn, both dialysis and ultra filtration cannot be performed at the same time.

Furthermore, Bonomini does not teach, allude to or render obvious using a plurality of dialysate sorbents to regenerate the dialysate on a completely wearable device. On the contrary, Bonomini is limited to teaching use of a single cartridge 31 that is charged with a single sorbent material, namely activated carbon. (Col. 5, lines 32-43) Bonomini does not teach, allude to or render obvious the use of “a plurality of dialysate sorbent devices for regenerating the dialysate wherein a first sorbent device contains a first sorbent and a second sorbent device that contains a second sorbent; said first sorbent and said second sorbent being different compounds”.

Applicant also respectfully points out that Bonomini does not teach, allude to or render obvious performing dialysis while performing ultra filtration. Applicant strongly and respectfully submits that Bonomini's ultra filtration is performed in its own phase and Bonomini's dialysis is performed in a separate phase. (Col. 6, lines 24-28) In the ultra filtration phase, "blood is drawn [by] the pump 13, whereas a reduced pressure is established in the dialyzer, on the dialysis liquid side, by means of pump 17, connected by shunt line 27 and line 29, to the outlet of dialyzer 10, while the output side of pump 17 is connected, via lines 19 and 22, to collection bag 21." (Col. 6, lines 29-36) Bonomini goes on to teach specifically that valves 26 and 28 must be suitably controlled to provide the ultra filtration fluid circuit. (Col. 6, lines 36-37) During the Bonomini dialysis phase, ultra filtration is not performed, instead only dialysis is performed when "valve 20 is switched to connect the output side of pump 17, via lines 19 and 23, to the inlet of the dialyzer, while valves 26 and 28 are switched to exclude shunt line 27, the circuit of the dialysis liquid then comprising filter cartridge 31, tank 24 and temperature control device 33." (Col. 6, lines 40-46) The dialysis phase then takes place for a predetermined time at the end of which the portable unit is disconnected from the patient's blood vessels and is ready for the next operation (presumably for the next patient). (Col. 6, lines 39-50) Bonomini teaches away from performing ultra filtration at the same time dialysis is performed. Bonomini clearly indicates that ultra filtration is not performed while the dialysis phase is being performed. Again, Bonomini teaches away from performing the ultra filtration phase and the dialysis phase at the same time. In particular, Bonomini states that the apparatus of the present invention, due to the complete separation between the ultra filtration and the dialysis phases, permits not only standard hemodialysis to be performed, but also ultra filtration alone and dialysis alone by merely suitably adjusting the circuit for the dialysis liquid. (Col. 7, lines 33-40) As such, Applicant respectfully points out that Bonomini does not teach, allude to or render

obvious “a microprocessor adapted to control a rate that excess fluid is removed from the dialysate while said at least one dialyzer is utilizing the dialysate to remove impurities from the blood” because Bonomini cannot perform both dialysis and ultra filtration at the same time and teaches away from doing so. (Col. 6, lines 39-50) Applicant also respectfully points out that performing ultra filtration and dialysis at the same time eliminates the need for any Bonomini-type valves and dual fluid circuits in embodiments of the present invention, further reducing the size and weight of the claimed invention and resulting in a structural difference between the claimed invention and Bonomini.

Bonomini does not teach, allude to or render obvious “a microprocessor adapted to control a rate that excess fluid is removed from said dialysate” in a completely wearable continuous renal replacement therapy device. Applicant would agree that, Bonomini teaches, and is limited to teaching, the electronic control of valves that enable a fluid circuit for the (1) ultra filtration phase or (2) dialysis phase. (Col. 6, lines 24-30) There is no suggestion in Bonomini to electronically control anything but a valve in a portable, non-wearable, ultra filtration or dialysis device. The Bonomini valves are used to switch operation of the device between ultra filtration and dialysis and are not taught or suggested to perform any other function.

With respect to independent claim 1 and independent claim 18, these claims are amended and recite a device that is “adapted to enable a patient to wear the whole device.” Claim 1 also recites that the microprocessor is “adapted to control a rate that excess fluid is removed from said dialysate while said at least one dialyzer is utilized to remove impurities from the blood”. As such, Applicant respectfully points out that Bonomini does not teach, allude to or render obvious each element of claim 1 and respectfully requests that this § 103 rejection be withdrawn.

Claims 2-4, 6, and 14-16 are either directly or indirectly dependent on claim 1 and claims 19-22 and 27-32 are either directly or indirectly dependent upon claim 18, and are therefore not rendered obvious for at least the same reasons as stated above with respect to claims 1 and 18. As such, Applicant respectfully requests that the § 103 rejection be withdrawn and submits that claims 2-4, 6, 14-16, 19-22 and 27-32 are ready for allowance.

Claims 5, 17, 20 and 33 were rejected under 35 U.S.C. § 103(a) as being rendered obvious by Bonomini in view of Henne (U.S. Patent No. 4,212,738).

Claims 5 and 17 are each directly dependent upon claim 1. Henne does not alleviate the inadequacies of Bonomini by providing any teachings about a continuous renal replacement therapy device “that is adapted to enable a patient to wear the whole device.” As such, Applicant respectfully submits that claims 5 and 17 are not obviated by Bonomini in view of Henne and respectfully requests that the § 103 rejection be withdrawn.

Claims 20 and 33 are each either directly or indirectly dependent upon claim 18. Again, Henne, like Bonomini, does not teach, allude to or render obvious a continuous renal replacement therapy device “that is adapted to enable a patient to wear the whole device.” Furthermore, Henne, like Bonomini, also does not teach, allude to, or render obvious a first sorbent device that contains a first sorbent and a second sorbent device that contains a second sorbent, wherein the first and second sorbents are different compounds. As such, Applicant respectfully submits that claims 20 and 33 are not obviated by Bonomini in view of Henne and respectfully requests that the § 103 rejection be withdrawn.

Claim 8 was rejected under 35 U.S.C. § 103(a) as being rendered obvious by Bonomini in view of Henne and further in view of Greenwood (U.S. Patent No. 4,897,189).

Greenwood, like Bonomini and Henne, does not teach, allude to, or render obvious a continuous renal replacement therapy device “that is adapted to enable a patient to wear the

whole device.” Claim 8, being indirectly dependent upon claim 1, is therefore not rendered obvious for at least the same reasons as stated above with respect to claim 1. Applicant respectfully requests that the § 103 rejection be withdrawn.

Claim 23 was rejected under 35 U.S.C. § 103(a) as being rendered obvious by Bonomini, in view of Scott (U.S. Patent No. 3,388,803).

Like Bonomini, Scott does not teach, allude to or render obvious a continuous renal replacement therapy device “that is adapted to enable a patient to wear the whole device.” Claim 23, being indirectly dependent upon claim 18, is therefore not rendered obvious by Bonomini in view of Scott for at least the same reasons as stated above with respect to claim 18. Applicant respectfully requests that this § 103 rejection be withdrawn.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,



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